PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

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PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/JP2004/012790	27.08.2004	27.08.2003

International Patent Classification (IPC) or both national classification and IPC
G01N21/35, G02B6/12

Applicant
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1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☒ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notifed the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

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Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was field, unless otherwise indicated under this item.

   ☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

   a. type of material:

   ☐ a sequence listing

   ☐ table(s) related to the sequence listing

   b. format of material:

   ☐ in written format

   ☐ in computer readable form

   c. time of filing/furnishing:

   ☐ contained in the international application as filed.

   ☐ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

Box No. II Priority

1. ☒ The following document has not been furnished:

   ☒ copy of the earlier application whose priority has been claimed (Rule 43*bis*.1 and 66.7(a)).

   ☐ translation of the earlier application whose priority has been claimed (Rule 43*bis*.1 and 66.7(b)).

   Consequently it has not been possible to consider the validity of the priority claim. This opinion has nevertheless been established on the assumption that the relevant date is the claimed priority date.

2. ☐ This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43*bis*.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.

3. Additional observations, if necessary:

Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	6, 10, 26
	No:	Claims	1-5, 7-9, 11-25, 27-31
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-31
Industrial applicability (IA)	Yes:	Claims	1-31
	No:	Claims	

2. Citations and explanations

see separate sheet

RE SECTION V

1. The present application relates to a device and a method for detecting a target substance in a fluid comprising a structure which is transmissive to electromagnetic radiation, comprises a periodic distribution of refractive index and which has a vacant portion through which the fluid is passed. The structure transmits / reflects incident electromagnetic radiation depending on its wavelength which in turn is dependent on the refractive index properties of a substance in the vacant portion. In preferred embodiments the structure is a fibre optic waveguide which has a periodic variation of refractive index in the radial direction and which has at least one through hole for the fluid to be investigated. The detection is preferably by means of band gap edge displacement, use of a defect level in the band gap, or a change in pathway of light.

   The following documents are referred to:

   D1=US2002191884; D2=US2002155592; D3=WO0250514; D4=US6532326; D5=US2002131737; D6=US6539155; D7=US2002118937.

2. CLARITY AND INTERPRETATION OF CLAIMS

   Although claims 1, 13, 18, 29 have been drafted as separate independent claims, they appear to relate effectively to the same subject-matter and to differ from each other only with regard to the definition of the subject-matter for which protection is sought and in respect of the terminology used for the features of that subject-matter. The aforementioned claims therefore lack conciseness and as such do not meet the requirements of Article 6 PCT.

   -"A vacant portion ... arranged regularly". Reference to a SINGLE portion does not appear to be consistent with regular arrangement.

   - "electromagnetic wave projecting means" . This does not necessarily include a source - it encompasses any component or system for affecting an electromagnetic

wave.

- "magnetic wave". This should be transverse electromagnetic wave and is non limiting since all electromagnetic waves have such a component.

- claim 13 "comprising a flow path". A flow path is merely a region of space - this wording is therefore, if at all, only marginally limiting.

- claim 29 " solid portion capable of transmitting an electromagnetic wave to form a refractive index distribution in the radius direction ". It is not apparent how the ability of the solid portion to transmit electromagnetic waves gives rise to formation of a refractive index variations in the radial direction.

- "crystal". This wording according to the description includes GLASS materials so that the limitation of "crystal" is not clear.

3. PRIOR ART

D1 (Figs. 1, 4-6) discloses a photonic bandgap silicon filter capable of binding and detecting biological molecules in a liquid or gas sample using e.g an antibody-antigen binding reaction with one of the pair immobilised on the walls of the pores of the photonic band gap crystal - the structure has a defect in the periodic structure to provide a sharp spectral feature in the bandgap or uses the band edge for sensitive detection. D1 (Claim 5) discloses the use of an ARRAY of such filter devices with respective functionalisation with biological targets to permit simultaneous detection of various biological targets wavelengths. The fluid to be analysed is passed through the parallel pores of the structure and is illuminated in a direction perpendicular to the flow.

D2 (Figs. 2-4) discloses an array of photonic bandgap fibres 310 each of which fibres comprises as shown in Figs. 2a, 2b a collection of silica rods in a desired pattern on a micron scale which acts as bandgap fibres. According to Fig. 4 the respective

photonic bandgap fibres are coated with respective biological trapping agents so as to be sensitive to different conjugate binding analytes e.g. antibodies or other microorganisms and the array permits simultaneous screening for several analytes using a colour matrix for fluorescent light emitted at the output ends of the fibres as detected by respective detectors 220 as in Fig. 2.

D3 (Figs. 1-3, 5, 7, 13a, 14) discloses a photonic bandgap structure having periodic passages used for optically analysing the composition of liquids. Fig. 1 shows the band gap structure of the photonic crystal; Fig.2 the illumination of a fluid flow 13 through the passages of the crystal and detection at detector 11; Figs. 3, 5 show various geometries of the passages in the band gap crystal (in Fig. 5 the prismatic shape gives rise to direction changes); Figs. 7a, 7b show illumination perpendicular and parallel respectively to the flow path; Fig. 12 shows the use of trapping material in the form of a catalytic convertor 38 on the side of the passages for chemically reacting with a substance in the fluid and the use of a single source to provide two light paths at different portion of the crystal; Fig. 14 show parallel illumination of different photonic crystal by the same light source using a beam splitter.

D4 (Fig. 5) discloses the use of an array of transverse-longitudinal optical resonators (TLIRs) each comprising a photonic band gap resonant structure and supporting various lasing lines corresponding to respective absorption lines of gases. The TLIRs are placed on a single die to realise a gas detector by passing the gas (e.g. simultaneously) through the TLIR cavities 400 and detecting the absorption at the different respective wavelengths using detectors 513-518 - a substantial reduction in output form the detectors identifying one or more gases.

D5 (paragraphs 0114-0115, 0077-0086; claims 1, 39-42) discloses the use of micro structured optical fibres comprising a core 1 and two dimensional periodic lattice of voids 2 providing polarisation sensitive photonic band gap effects for detecting substances in fluids which are passed through said voids altering the spectral transmission of the fibre. In preferred embodiments the inner void surface is comprised of a layer of material which alters in response to the liquid characteristics.

D6 (col 11, line 35 - col 12, line 15; col 21, lines 10-20; claims 51-54) is similar

disclosure to D5 and additionally includes the breaking of the periodicity of the photonic crystal by a defect to form a mode within the forbidden gap which can be used for sensing.

D7 (Figs. 1-2) discloses the use of a holey fibre having a highly periodic hole structure to generate a photonic band gap effect which is used for optical sensing of liquids.

5. NOVELTY

In view of the disclosure of the above documents and the interpretation of claims above, the following claims:

Claims 1-5, 8, 11-14, 16-20, 23. See D1;

Claims 1-3, 5, 8, 11-13, 15-20, 27-31. See D2;

Claims 1-4, 8-9, 11-19, 21-25. See D3;

Claims 1-4, 8-9, 11-19, 21-25, 28. See D4;

Claims 1-3, 7, 11-13, 15-20, 29-31. See D5;

Claims 1-3, 5, 11-13, 15-20, 29-31. See D6;

Claims 1, 3, 8, 11-13, 15-19, 29-30. See D7;

- together claims 1-5, 7-9, 11-25, 27-31 do not meet the requirement of novelty (Art. 33.2 PCT).

6. INVENTIVE STEP

Claim 6. Temperature control. The skilled person in the field sensing using optical fibre modes is aware that these are sensitively temperature dependent (fibres with optical modes are well-known as temperature sensors) and that temperature control would be necessary to avoid noise / falsification of the signal from the analyte in the fluid.

Claim 10. D3 (Fig. 10) discloses the use of a prismatic shaped bandgap structure for chromatically separating an incident light beam into a plurality of separate beams which are incident on respective detectors 37. To achieve this effect as efficiently as possible the skilled person would realise that the incident beam must be collimated in a particular direction (first aligning means) and that second aligning means such as apertures or beam splitters on the output side should be used.

Claim 26. Plural structures with non overlapping wavelengths. Both D1, and D4 disclose the use of arrays of photonic band gap structures which have different target wavelengths. Faced with the problem of maintaining a high signal to noise ratio the skilled person would preferably choose these ranges to be non overlapping.

Claims 6, 10, 26 therefore do not meet the requirement of inventive step (Art. 33.3 PCT).